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| 09/867,093 | 05/29/2001 | Eugene Bell | 13343-016002 | 6357 |

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FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER

ROBINSON, HOPE A

| ART UNIT | PAPER NUMBER |
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1653

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/867,093

Applicant(s)

BELL ET AL.

Examiner

Hope A. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/20/04.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,15,16,18,19,23-33,35,36,39,40,42,46 and 48-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,2,4-10,15,16,18,19,23-33,35,36,39,40,42,46 and 48-55 is/are rejected.
- 7) ☐ Claim(s) 56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's response to the Office Action mailed July 16, 2003 on January 20, 2004 is acknowledged.
2. Claims 3, 11-14, 17, 38, 41 and 47 are canceled. Claims 1, 4-5, 8, 15, 18, 20, 22-23, 28, 33, 39-40, 42, 44, 46, 49 and 53 have been amended. Claims 1-2, 4-10, 15-16, 18-19, 23-33, 35-36, 39-40, 42, 46 and 48-56 are pending and are under examination. Applicant is reminded that under the revised amendment practice the status identifiers are " original, currently amended, canceled, withdrawn, new, previously presented and not entered", there is no "previously amended" identifier as recited in claims 27 and 30.
3. The following grounds of rejection are or remain applicable:

Claim Objection

4. Claim 56 is objected to because the claim depends from a rejected based claim.

Specification

5. The disclosure is objected to because of the following informalities:

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The specification is objected to because trademarks are disclosed and they are not capitalized. The use of the trademark such as TRIS®, TEFLON® etc., has been noted in this application (see for example, pages 20 and 26). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Correction is required.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 4-10, 31-32, 37, 39, 42 and 48-49 remain rejected under 35 U.S.C. 112 second paragraph, as failing to particularly point out the subject matter which the applicant regards as the invention.

Claim 4 remains indefinite as to "between about" as between requires "within" and "about" permits going outside the bounds of the "between". Cancellation of one or the other is suggested (see also Claims 37 and 48). The claim is further indefinite for

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the recitation of the phrase "between about 1 to 500 μ m inclusive", because the word "inclusive" is open language similar to comprising and the word "between" sets a limit (see also claims 39, 42 and 48). Claim 4 is also indefinite because the amendatory language is confusing, the claim now recites "The composition of claim 1, wherein the calcium cement is in the form of granules with a of between about 1 to 500 μ m inclusive". The dependent claims hereto are also included.

Claim 10 is indefinite because the claim does not further limit amended claim 1 from which it depends; it is duplicative.

Claim 31 remains vague and indefinite for the recitation of the phrase "includes or is conditioned with cells" because it is unclear how a composition is conditioned with cells or how conditioned with cells is an alternative to inclusion of cells. Further, how are cells included in the composition? The dependent claims are included in this rejection (i.e. claim 32 with regard to mechanically conditioned). In addition claim 31 remains indefinite because the claim recites "and/or", and it is unclear as to whether the slash refers to "and/or" or just "or".

7. Applicant's arguments filed January 20, 2004 have been considered. Note that the rejection under 35 U.S.C. 112, second paragraph remains because applicant's arguments did not address the issues raised in the above claims. It is noted that the response on page 9 state that claim 31 for example, has been amended, however, the claim still recites "and/or", and "includes or is conditioned with cells", although amended in other claims (the dependent claims hereto have also not been amended). The

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"between about" language was amended in some claims not others; see for example, claims 4, 37 and 48. The issues raised regarding the language "inclusive" in the claims was not addressed in the response, thus remains. Note the new grounds of rejections made for example, over claims 4 and 10, are necessitated by the amendments made. Therefore, the rejection has been maintained.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-2, 4-10, 15-16, 18-19, 23-33, 35-36, 39-40, 42, 46 and 48-55 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bell et al. (U.S. Patent No. 5,891,558, November 21, 1996).

Bell et al. teach compositions mixed with calcium phosphate cement (claim 1) and methods for producing the same (claim 40), for example, -tricalcium phosphate cement which includes 64% -tricalcium phosphate, 16% calcium phosphate monobasic, 15% calcium sulfate hemihydrate (claims 2 and 15) and 5% calcium pyrophosphate (claim 15) to produce a reinforced cement (claim 36) for use as for example, orthopedic or dental implants (claim 1, column 15). Bell et al. teach a density of 300 micrometers, which falls within the range recited in claims 4, 39, 42 and 48 (column 2). Bell et al. teach a method of rebuilding bone, cartilage, tendon, and ligament (claim 46), using

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foams/foam compositions seeded with the appropriate cells (claim 5), for example, connective tissue cells such as osteocytes (claim 9), chondrocytes, types of mesenchymal cells as recited in claims 6 and 50 (column 8) and tendon and ligament fibrocytes (claim 8), and molded in the appropriate form to repair damaged connective tissue (claim 7, column 1). Bell et al. disclose compositions used in vitro, for example, for model systems for research, or in vivo as prostheses or implants to replace damaged or diseased tissues or to provide scaffolds which, when occupied by cells are remodeled to become functional tissues (see column 1). The reference also teaches biocompatible constructs which include single and double density biopolymer foams (claim 29) and extracellular matrix particulates (claim 55) and methods of preparing these constructs which can be used in tissue repair and reconstruction (claim 19, column 3). The extracellular matrix is said to play an instructive role in cell division, morphogenesis, differentiation, tissue building and regeneration (claim 18, columns 11 and 12). Furthermore, the reference teaches a preferred biopolymer (claims 23 and 52), collagen (an injectable vehicle, claims 10 and 51) such as porcine fetal collagen (claims 24 and 25, column 2). In addition, Bell et al. teach single density biopolymer foams (claim 26, column 2). Bell et al. disclose that foam compositions or collagen sponges have been used as hemostatic agents (claims 16 and 53) and more recently as scaffolds (mats, claim 28, column 3) for tissue repair in vivo as research tools and in vitro for seeding various cell types. Further Bell et al. teach microcompartments with walls, which include biopolymer fibers and or filaments (claim 27, column 6). Bell et al. teach a composite (claim 32) that consists of conditioned cells (claims 31 and 49, and the ability to contain other structures (claim 30), see column 6. Bell et al. disclose in Example 2, column 20 the use of pepsin in the extraction (claims 33 and 54) of collagen

(microfibrillar, claim 35) and buffered solution. Thus, the claims are anticipated by this reference.

9. Applicant's arguments filed January 20, 2004 have been considered, however, were not persuasive, therefore, the rejection under 35 U.S.C. 102(b) remains. The response states that the "Bell et al. reference does not disclose a calcium cement having the combination of β -tricalcium phosphate and calcium phosphate monobasic recited in the present claims, which recites a ratio by weight of about 1:2 to about 1:3.75". It is further stated that even if Bell et al. teaches the cement the ratio taught would be 4:1. Applicant's comments are not persuasive. Bell et al. teach calcium phosphate cement, i.e., beta-tricalcium phosphate cement that includes 64% beta-tricalcium phosphate and 16% calcium phosphate monobasic among other components such as calcium sulfate hemihydrate. As the claims have the open language "comprising" the other components taught by the reference is not an issue. With regard to the ratio, Bell et al. teaches a ratio of 1:4 (calcium phosphate monobasic (16%) to beta-tricalcium phosphate (64%)) not 4:1 as stated by applicant. The claims are directed to a ratio of "about 1:3.75", therefore a ratio of 1:4 falls within that range with the "about" language. Therefore, the rejection of record has been maintained.

Conclusion

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10. Applicant's amendment necessitated the new/modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. No claims are presently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday from 9:00 a.m. to 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low can be reached on 571-272-0951. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS 

Patent Examiner



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER